RETHINKING INFORMED CONSENT IN BIOETHICS

Informed consent is a central topic in contemporary biomedical ethics. Yet attempts to set defensible and feasible standards for consenting have led to persistent difficulties. In *Rethinking Informed Consent in Bioethics*, Neil Manson and Onora O'Neill set debates about informed consent in medicine and research in a fresh light. They show why informed consent cannot be fully specific or fully explicit, and why more specific consent is not always ethically better. They argue that consent needs distinctive communicative transactions, by which other obligations, prohibitions and rights can be waived or set aside in controlled and specific ways. Their book offers a coherent, wide-ranging and practical account of the role of consent in biomedicine which will be valuable to readers working in a range of areas in bioethics, medicine and law.

NEIL C. MANSON is Lecturer in Philosophy at the Institute for Philosophy and Public Policy, Lancaster University.

ONORA O'NEILL is Professor of Philosophy at the University of Cambridge. Her most recent publications include *A Question of Trust: The BBC Reith Lectures 2002* (2002) and *Autonomy and Trust in Bioethics* (2002).

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NEIL C. MANSON AND ONORA O'NEILL

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Preface

Informed consent is now widely seen as fundamental to medical and research ethics. This has not always been the case. Informed consent first rose to prominence in biomedical practice with the Nuremberg Code of 1947, which responded to the abusive treatment of human beings by Nazi medical researchers. Consent requirements were subsequently extended from research to clinical ethics, and more recently to procedures regulating the acquisition, possession and use of personal information, including genetic and medical information. Across the last fifty years informed consent requirements have also supposedly been made more rigorous: standards for 'consent disclosures' are now more exacting; demands for more explicit and more specific consent are widely endorsed; ever more elaborate consent forms are increasingly devised and required. This huge expansion and elaboration of informed consent requirements is generally seen as indispensable if we are to respect individual autonomy. Informed consent, it is argued, ensures that patients and research subjects can decide autonomously whether to permit or refuse actions that affect them.

Yet current approaches to informed consent have led to many problems. If patients and research subjects consent without reading or understanding informed consent 'disclosures' – and it is clear that they do – is their consent inadequate? If consent 'disclosures' omit certain information – and it is clear that they do – is consent given on the basis of such disclosures inadequate? Should we forbid medical treatment and research whenever informed consent is defective? Or should we persist with current consent practices, in the full knowledge

that defective consent will not ensure the autonomy of research subjects or of patients? Neither option is appealing.

In this book we consider how we might rethink the use of informed consent in biomedicine. We begin by exploring received views of informed consent, and the arguments usually given for requiring the consent of patients and research subjects to biomedical interventions. We try to identify and make explicit the underlying assumptions that shape contemporary thought, talk and debate about informed consent. We conclude that standard accounts of informed consent, standard arguments for requiring consent in clinical and research practice and standard ways of implementing consent requirements lead to intractable problems. We then propose an alternative, less ambitious, account which we hope and believe provides a more plausible account of the part that informed consent procedures can and should play in shaping ethically acceptable biomedical practice.

This approach to rethinking informed consent is not, perhaps, the obvious one; it is certainly not the preferred one. Most of the vast contemporary literature on informed consent in biomedicine looks for ways of improving informed consent procedures, typically by finding ways of making 'consent disclosures' more perspicuous or complete, and consent requirements more user-friendly for patients and research subjects. We think that these ameliorative approaches have limited potential, because they do not address the underlying difficulties of current conceptions of informed consent.

As we see matters, informed consent is sought and obtained by distinctive sorts of *communicative transactions*. We are unlikely to understand informed consent unless we consider the sorts of communicative transactions it requires and the standards they must meet. Many current accounts of informed consent represent such transactions quite passively, as a matter of *information transfer*. Information is seen as *located* or *held* in one or another place, or as *flowing* from one place to another. Information flows are seen as the *transfer* or *transmission of* information from one *source* or *container* to another, through one *conduit* or *channel* or another. These metaphors have their uses: they provide a common vocabulary for discussing

the transfer of information between technological devices and between people. But they also have their dangers: they encourage us to think of information in abstraction from human activity, and specifically in abstraction from the normative framework that governs successful communicative transactions between people.

Many current discussions of informed consent are shaped by these impersonal metaphors. For example, discussions of informed consent requirements often focus narrowly on the proper 'disclosure' of information by clinicians and researchers; discussions of patient privacy often focus narrowly on requirements to 'process' medical data in prescribed ways. Yet if we rely on these impersonal metaphors we may miss matters that are basic to communicative transactions between people, including the transactions by which they request, give and refuse consent.

A more plausible and illuminating framework for thinking about informed consent would start from the fact that the communicative transactions by which it is sought, given or withheld are rationally evaluable social transactions between agents. They include or consist of speech acts. Speech acts are governed and constrained by a rich normative framework, and fail in various ways if the relevant norms are ignored or flouted. So any convincing account of informed consent transactions must begin by considering the epistemic and other norms that must be observed for successful communication. We identify many of these norms, and discuss the part they play in shaping the successful use of informed consent transactions to permit clinical or research interventions that would otherwise be unacceptable.

In successful informed consent transactions, communication is used to *waive* specific ethical, legal or other rights, obligations or prohibitions. Such transactions therefore presuppose the rights, obligations and prohibitions that are to be waived. So the obligations of medical practitioners and researchers to inform patients and research subjects, and to seek their consent to specific interventions, are always *secondary* obligations. Our rethinking of informed consent sets out the standards that communicative transactions must meet if they are to be used to waive obligations, rights and

prohibitions in specific ways. Properly used, informed consent can render action permissible that would otherwise constitute (for example) assault, false imprisonment, deception, or some other breach of significant ethical requirements.

We take a parallel approach to the use of informed consent transactions in contemporary debates about specifically informational obligations, including those grouped under headings such as *information privacy* and *genetic privacy*, *data protection* and *right to know*, *accountability* and *transparency*. Many current debates about informational obligations begin with the thought that certain classes of information have intrinsic and distinctive ethical importance. On the one hand they see personal information, including personal, medical and genetic information, as information that nobody else has a right to know, which should be kept inaccessible unless there is informed consent to its disclosure. On the other hand they see institutional information, and in particular information about institutional and professional performance, as information that everybody else has a right to know, which should be disclosed in the name of transparency, accountability and freedom of information.

We argue against such views that informational obligations are not best understood by trying to identify rights over putative classes of information. Informational obligations are better articulated in terms of ordinary epistemic and ethical requirements on communicative transactions. Respect for others' privacy is best seen as a set of requirements on communicative transactions, rather than as requirements that certain types of information be kept inaccessible. Demands for accountability are best seen as requirements on communicative transactions that offer and take account of past action, rather than as requirements that certain types of information be transparently and universally 'available'. Where informational obligations are construed simply as a matter of keeping types of information hidden or making it available, there is a real danger that we adopt and require institutional policies and practices which are of little use, or even damaging to biomedical practice – and beyond. Where they are construed as a matter of epistemically and ethically acceptable communication, there is at least a possibility of establishing policies

and practices that support rather than undermine good practice, and that may help secure or restore trust, in biomedicine – and beyond.

The approach that we take to informed consent is not novel or unfamiliar. It is a matter of emphasising the continuing importance of norms of intelligibility, relevance, accuracy and honesty (and other norms) in all communicative transactions, rather than of demanding ever fuller or better consent 'disclosures', or ever tighter control of certain types of data. The conclusions we reach challenge a number of current orthodoxies. We suggest that informed consent is best thought of as part of a wider ethics of communication. We argue that informed consent does not and cannot offer free-standing ethical justifications, but rather is used to waive other, more basic ethical standards (which informed consent requirements invariably presuppose). We show why informed consent cannot, *a fortiori* should not, aim to be fully specific or fully explicit. We argue that some of the informed consent requirements that have been built into contemporary legislation and codes (ranging from legislation governing Data Protection to the Declaration of Helsinki) are implausible, even incoherent. More positively, we believe that the approach we propose provides a clear and convincing account of the purposes of informed consent requirements in biomedicine and of the standards that they should meet.

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